

JAN 28 2004

K032263



Summary of Safety & Effectiveness

COMPANY: Implant Innovations, Inc.
4555 Riverside Drive
Palm Beach Gardens, FL 33410

CONTACT: Jeannette G. Dailey, RAC
Regulatory Affairs Manager
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DATE PREPARED: July 21, 2003

NAME OF THE DEVICE: *3i* Patient-Specific Dental Abutment
3i Patient-Specific Overdenture Bar

CLASSIFICATION: DZE Class III

COMMON NAME: Dental Abutments

PREDICATE DEVICES: The *3i* Patient-Specific Dental Abutments and Overdenture Bars are substantially equivalent to dental abutments and overdenture bars currently on the market in overall design and intended use.

Predicate devices include:

K012911
LOCATOR Anchor System

K991947
3i Ceramic Abutment System

K980083
3i Orthodontic Abutment Systems

K965077
3i Single Tooth Abutment System

K962465
3i Abutment & Retaining Screw System

K932123
3i Pre-Angled Abutment System

K933462
3i Conical Abutment System

K933969
3i Tapered Abutment System & Components

K934126
3i One and Two Piece Temporary Healing
Abutments

K891613
3i Overdenture Attachments

K871863
3i Dental Implant Abutment Systems

K974150
Nobel Biocare, Inc.
Procera® Preparable Abutment System

K981858
Atlantis Components, Inc.
Atlantis Abutment and Screw

DEVICE DESCRIPTION:

The *3i* Patient-Specific Dental Abutments and Overdenture Bars are designed to match individual patients.

INDICATIONS FOR USE:

The *3i* Patient-Specific Dental Abutment and Overdenture Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support

single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

SUMMARY OF SAFETY AND EFFECTIVENESS:

Safety and effectiveness problems that have been encountered with similar abutment systems used with endosseous implants may include occasional fractures of the screw; screws becoming loose; or improper mating resulting in inflammation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2004

Ms. Jeannette G. Dailey
Regulatory Affairs Manager
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K032263

Trade/Device Name: *3i* Patient-Specific Dental Abutments and Overdenture Bars
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: October 29, 2003
Received: October 30, 2003

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

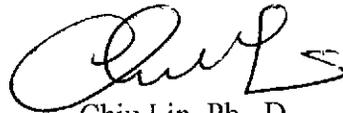
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph., D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: 3i Patient-Specific Dental Abutments and Overdenture Bars

Indications for Use:

The 3i Patient-Specific Dental Abutment and Overdenture Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division 510(k))
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K032263

Prescription Use: _____
(Per 21 CFR 801.109)

OR

Over the Counter Use: _____